

REMARKS

Claims 9-24 are currently pending in this application. Claims 1-8 were previously canceled without prejudice or disclaimer. Claim 9 is amended to recite “[a] method of treating ischemic tissues, comprising administering activated Factor XIII and thereby stimulating the perfusion of ischemic tissues” and claim 14 is amended to recite “[a] method of treating ischemic tissues, comprising administering activated Factor XIII and thereby stimulating the proliferation of new blood vessels in ischemic tissues.” Support for these amendments can be found throughout the specification, *e.g.*, at the Title and Abstract; on page 3, lines 5-7; on page 7, lines 21-33; and in the Examples. The specification is amended herein to recite the priority information for this application. No new matter has been added by these amendments.

OBJECTION TO THE SPECIFICATION

The Examiner objects to the specification as allegedly failing to comply with 37 C.F.R. § 1.78. Office Action at Item 5. Specifically, the Examiner contends that “[t]he priority information should be included in the first paragraph of the specification.” *Id.* The specification is amended herein to recite the priority information for this application. Accordingly, Applicant respectfully requests that this objection be withdrawn.

REJECTION UNDER 35 U.S.C. § 102(b)

Claims 9-24 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 98/51333 to Deisher et al. (“*Deisher*”). Office Action at Item 7. Applicant respectfully traverses.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P.

§ 2131 8th Ed., Aug. 2007 Rev. (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); emphasis added). Applicant submits that *Deisher* cannot anticipate the instantly claimed invention because each and every element as set forth in the claims is not found in that reference.

Currently amended claim 9 recites “[a] method of treating ischemic tissues, comprising administering activated Factor XIII and thereby stimulating the perfusion of ischemic tissues.” In contrast, as the Examiner admits, *Deisher* teaches methods for “reducing ischemic reperfusion injury and reducing necrotic tissue damage and/or vascular injury resulting from ischemic reperfusion by administration of factor XIII.” Office Action at p. 3 (emphasis added); see also *Deisher* at p. 9, ll. 28-29 (“reduction in tissue damage or vascular injury following restoration of blood flow (reperfusion)”) (emphasis added). Reperfusion injury occurs when a blood vessel (*e.g.*, an artery), which has been occluded for a certain time, is perfused with blood after reopening. Such reperfusion is followed by an inflammatory reaction inside the vessel, as the complement and coagulation systems are activated, liberating cytokines and inflammatory cells, such as macrophages, which transmigrate from the vessel causing edema and organ damage. See *e.g.*, *Deisher* at p. 1, ll. 20-p. 3, ll. 17. *Deisher* claims that Factor XIII is able to reduce this reperfusion injury. See *Deisher* at claim 1. Thus, *Deisher* teaches the administration of Factor XIII after reperfusion of ischemic tissues in order to reduce ischemic reperfusion injury. In contrast, currently amended claim 9 is directed to a method of initiating (*i.e.*, stimulating) the perfusion of ischemic tissues. Thus, *Deisher* fails to teach all of the elements of claim 9.

Currently amended claim 14 recites “[a] method of treating ischemic tissues, comprising administering activated Factor XIII and thereby stimulating the proliferation of new blood vessels in ischemic tissues.” In contrast, *Deisher* provides no teaching, either express or inherent, of any proangiogenic effects of activated Factor XIII in ischemic tissue. Instead, *Deisher* focuses entirely on the role of Factor XIII in blood coagulation, reducing blood loss, and preventing tissue damage after reperfusion, none of which relate to the use of activated Factor XIII for stimulating the proliferation of new blood vessels in ischemic tissues, as recited in currently amended claim 14. See *Deisher* at p. 5, ll. 10-13; p. 6, ll. 19-20; and p. 7, ll. 5-10. Thus, *Deisher* fails to teach all of the elements of claim 14.

The Examiner contends that “the phrase in claims 9 and 14 in reference to a method of ‘stimulating the perfusion of ischemic tissues’ is an intended use and it is not a limitation to the instant one step method.” Office Action at p. 4. Applicant respectfully disagrees. As discussed above, the instantly claimed invention is based in part on Applicant’s novel discovery that a Factor XIII-preparation “can be used for the stimulation of the perfusion of ischemic tissues by the proliferation of new blood vessels.” Specification at p. 3, ll. 5-8. Currently amended claims 9 and 14 recite these inventive elements, which distinguish the currently pending claims over the prior art. Accordingly, the reference in claim 9 to “stimulating the perfusion of ischemic tissues,” which is no longer in the preamble, and the reference in claim 14 to “stimulating the proliferation of new blood vessels in ischemic tissues,” should be interpreted as a required elements of those claims.

The instantly claimed invention is directed to a method of treating ischemic tissues comprising administering activated Factor XIII to stimulate the proliferation of new blood vessels after a disturbed perfusion of blood. These inventive aspects are recited in the currently amended claims. In contrast, *Deisher* does not teach, either expressly or inherently, the administration of activated Factor XIII in order to stimulate the perfusion of ischemic tissues, or that Factor XIII can induce the proliferation of new blood vessels, as required by the currently amended claims. Thus, *Deisher* and the instant application describe two different and independent physiological mechanisms influenced by Factor XIII. Accordingly, since *Deisher* fails to teach a method of stimulating “the perfusion of ischemic tissues” or “the proliferation of new blood vessels in ischemic tissues,” as required by the currently pending claims, *Deisher* cannot anticipate the instantly claimed invention.

For at least these reasons, Applicant respectfully requests that the rejection of claims 9-24 under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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